I. Goals

This track combines the foci of four tracks at the previous National Health Information Infrastructure (NHII) meeting in 2003: architectures, standards, vocabulary, and safety and quality (decision support). This track is concerned with architecture and standards for the sharing of information between health information systems served by the proposed NHII. The focus is on the integration of information where needed to enable the nation to achieve the best possible health outcomes. We identify four primary drivers and kinds of integration, all of which require interface/interaction among heterogeneous systems and applications (see Fig. 1).

- **Continuity of health records over a patient’s lifetime.** The goal is to provide continuity of care and its documentation in health records for a patient throughout his/her lifetime, independent of the institutions or practices that are involved for particular episodes of health care. This includes the ability for patients/consumers to document personal health interventions and disease prevention actions. An important aspect of attaining continuity is the provision of mechanisms for secure data exchange and identification of persons, places and organizations in a way that allows integration and visualization of a patient’s lifetime data at the point of care.

- **Collaborative service provision.** The goal is the coordination of health-related tasks among independent organizations or individuals that take part in particular episodes of health care. Examples include processing of patient orders, specialty referral and consultation, communication and processing of prescriptions and post-operative home care follow up.

- **Integration of knowledge for decision support.** The goal is to facilitate the context-appropriate, patient-specific application of high quality knowledge resources for decision support in the above two activities, continuity of health records over a lifetime and collaborative service provision. Various kinds of support may be aimed at doctors, nurses, other care providers and patients themselves. Purposes are to reduce errors, promote best practices and foster cost-effectiveness.
• Aggregation of health information over a population. The goal is to foster aggregation of health information across patients, outcomes research, health services research, predictive modeling and public health surveillance and monitoring.

The objective of this Architecture and Standards Track will be to identify a small number of priorities on which NHII should focus in the short range (2-5 year time frame) in order to establish the architecture and standards that are critical to its realization.

II. Summary of NHII 03 background and recommendations on architecture, standards, vocabulary, and safety and quality

Participants in the architecture, standards, and vocabulary breakout sessions of the NHII 2003 made a number of short- and medium-term recommendations for improving the nation’s information system architecture. These included creation of a national task force with an architecture workgroup; creation of financial incentives to encourage the continued adoption of key standards, such as the HL7 messaging standard, DICOM, NCPDP, SNOMED and LOINC; development of implementation guides and associated conformance tests and tools, agreement on a concept-to-model continuum, creation of common terminology services, creation of regional committees to make recommendations for local communities and regions; creation of multi-organization demonstration projects that include all patient settings and that extend beyond a single region; a focus on important architectural principles, including unique identification of patients and providers with attention to security; and application of Consolidated Health Informatics (CHI) initiative standards to labeling of data at their source.

Recommendations from the safety and quality breakout session included a shared repository of rules in computable format that facilitate decision support and patient safety; standardization of patient safety reports; improvement in automated adverse event detection; and creation of an accessible patient “mini-record” by a trusted authority.

In addition, other breakout groups made several recommendations pertinent to standards. These included characterization of organizations’ business process models in order to identify the best fit for standards; provision of funding for those developing standards in order to increase the speed of their development and create a robust process for their maintenance that addresses issues that arise during practical use; decrease barriers and increase benefits to adoption of standards, including common terminology services; standardization of standards in terms of publication format, electronic availability of standards and financial rewards for their use; designation of a core set of standards; identification of important inter-relationships, including those between clinical and administrative terminologies as well as between terminologies and concept models; and continuation of the CHI process.

III. Achievements during the past year

We identify the following major achievements that provide impetus to the architecture/standards agenda:

• Adoption of SNOMED CT by the US Government to provide no-cost licenses for all US users
• Growing recognition of the importance of EHRs by government and other stakeholders
• Establishment of Health IT leadership as a national priority and establishment of the Director of Health Information Technology as a sub-cabinet-level position in the US Department of Health and Human Services (DHHS)

• In HL7 as a key standards development organization, progress on adoption of standards for decision support: evolution of Arden Syntax, first committee ballot on GELLO and a draft “infobutton” proposal

• The NIH Roadmap Initiative, fostering integrated multi-disciplinary approaches to information infrastructure for basic and clinical research, and for technology transfer to clinical practice

• CaBIG program of NCI to develop and provide infrastructure for clinical trial networks

• The CHI inter-agency collaboration endorsement of further standards, including HL7’s Clinical Document Architecture, SNOMED CT for identification of diagnoses, NLM’s RxNorm for identifying clinical drugs, the HUGN for identifying genes and the EPA Substance Registry System for identifying non-medicinal chemicals

• In further work in HL7, proposal of the EHR Functional Model, which has attained the status of a draft standard for trial use (DTSU), providing a common vision of the functions of EHR systems

• IHE (Integrating the Healthcare Enterprise) expanded to define standards-based Integration Profiles for cardiology, laboratory, radiology and IT Infrastructure. IHE and HL7 joint demonstration with the involvement of more than 30 vendors at HIMSS of the effective use of IHE Integration Profiles and a wide range of HL7 current and emerging standards.

• HL7 V2.5 messaging standard approved

• Tenth anniversary of DICOM, one of the CHI-endorsed standards. Cited as best practice in healthcare standardization for world-wide adoption and pervasive use in most imaging specialties.

• HL7 Common Terminology Services standard approved.

IV. Approach/Recommendations

Given the large number of recommendations from the previous year’s tracks and the lack of specific responsible parties for some of them, we recommend that this year the focus should be on a limited number of recommendations that are actionable in the relatively short term.

We recognize that a single architecture will not be possible for the wide variety of health information systems and the different purposes that many of them, or their components, address. Nevertheless, a number of points of contact and types of interactions of these systems with other systems need to be facilitated. The NHII architecture and standards should apply to the touch points between the health information systems of the organizations that support care delivery and the NHII information systems (see Fig. 2). Facilitation of information sharing across these points of contact will promote the integration of information that in turn leads to the achievement of the four major goals identified: (a) Continuity of health records over a patient’s lifetime, (b) Collaborative service provision, (c) Integration of knowledge for decision support, and (d) Aggregation of health information over a population. Although not shown in Fig. 2, a number of key infrastructure-
supporting services are also critical to ensure privacy/security, including data compatibility, vocabulary management, etc.

We believe that the best way to achieve progress, therefore, is to focus on specific transactions for services that are essential to these four categories of functionality, to prioritize them, and to foster agreement on methods for performing them. These methods will rely on well-defined, standards-based communication between one system/application component and another, and can be evaluated by performance against reference implementations of the transactions. In early years, the focus can be on important yet relatively basic transactions and in later years can focus on more sophisticated ones. As the community of users/health care organizations and implementers/vendors reach agreement each year on goals, the level of capability for interoperability will continually grow.

Three primary and four enabling recommendations for consideration by the breakout sessions are as follows:

**Primary Recommendations**

1. Unambiguously identify and describe key services and transactions of the NHII, in terms of actors and resources needed, and create standards-based reference implementation guides for these to be used as industry benchmarks for interoperability. The core activity of creating implementation guides or integration profiles is to tightly bind standard coded terminologies to the existing data exchange standards. The process for creating integration profiles should be consistent with the IHE initiative and with HL7 practices. The proposal is to significantly expand these activities and promote integration profiles as a central strategy for interoperability. These NHII-related integration profiles should support transactions ensuring that knowledge-based decision support is enabled.

2. Create high-quality content libraries of knowledge resources (evidence-based and peer-reviewed) for the decision support transactions (such as rule libraries and clinical order sets) that are in standard formats. Identify Federal or other means for creating and distributing them that maximizes their accessibility. Tools for authoring, editing and updating content should also be developed and disseminated.

3. Establish a consortium of stakeholders, rules of governance, and business model for facilitating goal setting, prioritization, and implementation of the above initiatives.
Enabling Recommendations

4. Create a process for assigning and maintaining **unique identifiers** for patients, providers, health care facilities, and other health care related entities. These identifiers are essential if data and information are to be shared among heterogeneous systems and throughout the lifetime of the patient.

5. Establish **standard encodings** of data at the original sources. For example, require that laboratory test kits or bedside instruments export data using LOINC codes, and that problem and diagnosis data be entered using SNOMED codes. This will require continued support for expanding and enhancing LOINC, SNOMED, RxNorm, FDA drug identifiers, and other code sets so they are comprehensive for clinical data capture.

6. Create a conformance testing process (e.g., IHE Connectathon) where messages, applications, and tools can be evaluated for adherence to standards and the integration profiles. Software testing processes that identify incorporation of and compliance with these integration profiles should assist vendors and purchasers of software to direct their resources toward those systems that offer the best opportunity for interoperability.

7. Define and establish an infrastructure to facilitate implementation of security and privacy mechanisms, such as security and data clearinghouses that simplifies integration of all of a patient’s health information at the point of care.

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